

Reply Under 37 C.F.R. § 1.111  
Date: June 22, 2006

Serial No. 10/715,639  
Atty. Docket No. GP106-09.DV3

### Remarks

Claims 1-3, 5-11 and 13 are presently pending in the subject application.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

The specification has been amended herein to update priority information.

Claims 4, 12 and 14-25 have been canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application.

Claim 1 has been amended herein to further recite a specimen retrieval device that is contained within a vessel having a pierceable cap that is fixed onto the open end of the vessel. Claim 1 has also been amended herein to indicate that the cap positions the specimen retrieval device along an inner surface of the vessel in such a manner that the specimen retrieval device does not significantly interfere with the movement of a fluid transfer device into or out of the claimed collection device. Support for these amendments can be found in the specification at, for example, the paragraphs bridging pages 10 and 11 and 20 and 21.

The dependencies of claims 5, 7 and 10 have been amended herein to reflect the cancellation of claim 4. Claims 3, 6 and 11 have been amended consistent with the amended language of claim 1. And claim 7 has been amended consistent with the original language of claim 9.

Claim 10 has been further amended herein to recite that the cap has a generally conical inner wall. This amendment is supported in the specification *passim*.

### Rejection Under 35 U.S.C. § 112

Claims 7, 8, 20 and 21 have been rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner contends that these claims are unclear because they do not indicate whether the recited wick is located in the cap or the container. To clarify, Applicants have amended claim 7 to indicate that the wick is located in the cap. Accordingly, Applicants submit that the claims are definite and withdrawal of this rejection is hereby respectfully requested.

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**Rejection Under 35 U.S.C. § 102**

Claims 1 and 4-6 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Miramanda (U.S. Patent No. 4,515,752). Applicants note that Miramanda does not disclose all of the limitations of amended claim 1 (*e.g.*, specimen retrieval device), as required under Section 102. Accordingly, withdrawal of this rejection is respectfully requested.

**Rejection Under 35 U.S.C. § 103**

Claims 2, 3, 10-19 and 23-25 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Miramanda (U.S. Patent No. 4,515,752) in view of Kezes *et al.* (U.S. Patent No. 4,803,998). Applicants respectfully traverse this rejection for the reasons that follow.

Miramanda is cited by the Examiner for disclosing a container having a cap with downwardly positioned segments and an inner wall of a container that form a means for positioning a specimen retrieval device along the inner wall of the container. The Examiner concedes that Miramanda does not teach a specimen retrieval device nor the striations of claim 10, but nevertheless points to Kezes for teaching a swab positioned in a vial that is sealed with a cap and argues that slits and striations were both conventional means for providing pipette tips access to capped containers.

In fact, Miramanda discloses a stopper that is fully inserted into a container and is provided with a number of protuberances or rings for adapting the stopper to an inner surface of the container. *See* Miramanda at col. 2, lines 27-30, and FIG. 3. The stopper is not designed to be removed for sample addition, and Miramanda does not teach how this could be done without contaminating either the user or the container. To the contrary, Miramanda states that “[t]he stopper allows fluids to be inserted in or removed from the interior of containers such as test-tubes, without having to remove the stopper.” *See* Miramanda at col. 2, lines 9-12 (emphasis added). Thus, the modification being proposed by the Examiner would impermissibly change the principal of operation of the Miramanda stopper and container. *See* MPEP § 2143.01 at 2100-132 (8<sup>th</sup> ed., Rev. 2, May 2004).

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Additionally, Miramanda illustrates that when a tubular member is inserted into the container, it forces the segments of the stopper against the side wall of the container, which could interfere with the opening of the stopper if a specimen retrieval device was present in the container. See Miramanda at FIG. 3. Also, as acknowledged by the Examiner, Miramanda teaches slits rather than striations in the cap. The Examiner's conclusion that "striations" were conventional in the art at the time of the claimed invention is unsupported by any evidence of record. Furthermore, the Examiner's own obviousness determination is contradicted by the concluding statement that "[i]t would have been obvious to one of ordinary skill in the [art to] substitute the *slits* of Miramanda for *score lines* since score lines would not immediately pierce the cap and jeopardize the contents of the container." (Emphases added.) Thus, the Examiner has actually determined that the striations of the claimed invention would not have been an obvious substitution for the slits of Miramanda.

Kezes does not cure the problems of Miramanda, as Kezes teaches neither a pierceable cap nor a specimen retrieval device positioned along an inner surface of a container. Rather, Kezes teaches a cap that captures the shaft of a swab at the axis of the cap to limit contamination. See, e.g., Kezes at col. 3, line 18 *et seq.* In Kezes, the swab is removed from the vial when the cap is removed by the end-user, whereas the claimed invention permits the end-user to access the contents of the container without removing the cap and without interference from a specimen retrieval device.

For the reasons presented above, Applicants submit that the presently claimed invention is fully patentable in view of the cited art, when considered separately or in combination. Accordingly, withdrawal of the Examiner's Section 103 rejection is hereby respectfully requested.

#### Allowable Subject Matter

Claims 9 and 22 are objected to as being dependent upon a rejected base claim. Applicants thank the Examiner for the indication that these claims would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claims.

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Applicants decline the Examiner's invitation to rewrite the claims at this time, as the claims are believed to be fully patentable for the reasons set forth above.

**Conclusion**

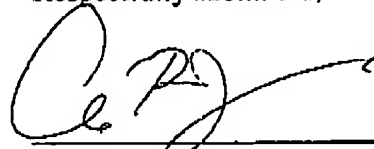
In view of the above amendments and remarks, Applicants submit that the subject application is in condition for allowance and notice to that effect is respectfully requested.

No fee is believed due in connection with this Reply. If Applicants are mistaken, then please charge any amounts due to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully submitted,

Date: June 22, 2006

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